K012523

OCT 26 2010

510(k) Summary

Applicant's Name/Address:	**Medtronic Neuromodulation** 7000 Central Ave., N.E. Minneapolis, MN 55432
Contact:	Trishia Dwyer Regulatory Affairs Specialist Medtronic Neuromodulation tel: (763) 526-3994 fax: (763) 526-6246 email: trishia.dwyer@medtronic.com
Date Prepared:	September 02, 2010
Name of Device:	Medtronic Model 355531 Multi-Lead Trialing Cable
Common Name:	Cable
Classification Name:	GZB (21 CFR 882.5880) GZF (21 CFR 882.5870)
Predicate Device:	The predicate device for the Medtronic Model 355531 Multi-Lead Trialing Cable is the currently available Medtronic Model 3550-03 OR Screener Cable (Twist Lock).
Device Description:	The Medtronic Model 355531 Multi-Lead Trialing Cable serves as an electrical connection between an external, temporary power source (e.g. screener or external neurostimulators) and a Medtronic neurostimulation lead or extension.
Intended Use:	The Medtronic Model 355531 Multi-Lead Trialing Cable (MLTC) is indicated for use with Spinal Cord Stimulation (SCS) and Peripheral Nerve Stimulation (PNS) systems for the treatment of intractable pain of the trunk or limbs.
Summary of Testing	Design Verification and Design Validation: Design Verification Testing and Design Validation Testing were performed to support substantial equivalence to the predicate device. All specified design and performance requirements were met, and the device was found to meet the user needs and intended uses.

Sterilization: The Model 355531 Multi-Lead Trialing Cable is labeled Sterile. The Model 355531 Multi-Lead Trialing Cable will be sterilized using the same 100% Ethylene Oxide (EtO) sterilization process as the predicate device.

Biocompatibility: All device materials and components were assessed for biocompatibility consistent with ISO 10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing." All materials were found to be compliant with ISO 10993-1.

Substantial Equivalence

Testing and supporting documentation have demonstrated that the Model 355531 Multi-Lead Trialing Cable is substantially equivalent to the previously cleared Model 3550-03 OR Cable (Twist-Lock Screening Cable). There is no change to the indications, intended use, or technological characteristics.

A summary of the Device Characteristics is included in the table below:

Description	**Predicate Device: Cleared 3550-03 OR Screening Cable**	**Subject Device: Model 355531 Multi-Lead Trialing Cable**
Market Release Information	K960631	K102523 (Subject device)
Indications for Use	The Medtronic Model 3550-03 OR Screening Cable is indicated for use with Spinal Cord Stimulation (SCS) and Peripheral Nerve Stimulation (PNS) systems for the treatment of intractable pain of the trunk or limbs.	The Medtronic Model 355531 Multi-Lead Trialing Cable (MLTC) is indicated for use with Spinal Cord Stimulation (SCS) and Peripheral Nerve Stimulation (PNS) systems for the treatment of intractable pain of the trunk or limbs. (Equivalent)
Fundamental Technology	External neurostimulation delivered to the lead electrodes.	External neurostimulation delivered to the lead electrodes. (Equivalent)
Design	Houses a lead to facilitate electrical connection	Houses multiple leads to facilitate electrical

Description	Predicate Device: Cleared 3550-03 OR Screening Cable	Subject Device: Model 355531 Multi-Lead Trialing Cable
	between the ENS and the lead.	connection between the ENS and the leads.
Lead Slots	1 octapolar -8 active electrodes	2 octapolar plus 4 quadrapolar -16 active electrodes

Conclusion

Through data and information presented, as well as similarity to legally marketed devices, Medtronic, Inc. considers the Model 355531 Multi-Lead Trialing Cable to be substantially equivalent to legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Medtronic Neuromodulation
c/o Ms. Trishia Dwyer
Regulatory Affairs Specialist
7000 Central Ave., N.E.
Minneapolis, MN 55432

OCT 2 6 2010

Re: K102523
Trade/Device Name: Medtronic Model 355531 Multi-Lead Trialing Cable
Regulation Number: 21 CFR 882.5880
Regulation Name: Implanted Peripheral Nerve Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: GZB, GZF
Dated: September 24, 2010
Received: September 27, 2010

Dear Ms. Dwyer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K102523

Indications for Use

OCT 26 2010

510(k) Number (if known): K_____

Device Name: Medtronic® Model 355531 Multi-Lead Trialing Cable

Indications for Use: The Medtronic Model 355531 Multi-Lead Trialing Cable (MLTC) is indicated for use with Spinal Cord Stimulation (SCS) and Peripheral Nerve Stimulation (PNS) systems for the treatment of intractable pain of the trunk or limbs.

Prescription Use ____X____ AND/OR Over-the-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

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